MAXIMUS Federal Services

Case Number:	CM15-0172837		
Date Assigned:	09/15/2015	Date of Injury:	03/11/2008
Decision Date:	12/18/2015	UR Denial Date:	08/08/2015
Priority:	Standard	Application Received:	09/02/2015

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:
State(s) of Licensure: Florida, New York,
Pennsylvania Certification(s)/Specialty: Family
Practice

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 50 year old female, who sustained an industrial injury on 03-11-2008. She has reported subsequent neck, bilateral shoulder, low back and right ankle and was diagnosed with lumbosacral, right ankle, cervical and bilateral shoulder sprain and strain, L5-S1 lumbar disc derangement and chronic pain syndrome. Treatment to date has included pain medication and physical therapy. The documentation submitted is minimal and the history of prescribed medications and the effect of those medications on pain and function were not documented. In a progress note dated 07-13-2015, the injured worker reported frustration with the lack of progress in her care and was noted to be dealing with pain and depression without any medication. The physician noted that the injured worker was having a severe flare up of pain that was rated as 7-9 out of 10 with associated severe depression and was noted to wish to resume her medication. Pain was noted to limit her daily activities and the injured worker reported spending a lot of time in bed. The injured worker noted that her previous, her prescribed medication was very helpful in providing her adequate pain relief and keeping her functional. Objective examination findings revealed moderate to severe tenderness to palpation over the L4-L5 and L5-S1 lumbar interspaces, muscular guarding over the bilateral erector spinae region, range of motion of the lumbar spine between 50-60% of the normal range, tenderness over the right lateral ankle with slight limited range of motion in flexion at 70% of the normal range and diminished muscle strength in the right knee to flexion and extension and in right ankle flexion and extension. Work status was documented as permanent and stationary. The physician noted that the injured worker would be restarted on pain medication utilizing Ultracet for breakthrough pain, Anaprox for anti-inflammatory treatment of her back and ankle and Prilosec

for gastritis. The physician also indicated that the injured worker would benefit from evaluation for chronic pain functional rehab program to improve her pain and function. A request for authorization of 60 Ultracet 37.5-325 mg, 60 Naproxen (Anaprox) 550 mg, 60 Prilosec 20 mg and one consultation-evaluation for chronic pain functional rehab program was submitted. As per the 08- 08-2015 utilization review, the aforementioned requests were non-certified.

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

60 Ultracet 37.5/325mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Introduction, Acetaminophen, Chronic pain programs (functional restoration programs), NSAIDs, specific drug list & adverse effects, Opioids (Classification), Opioids for chronic pain, Opioids for neuropathic pain.

Decision rationale: The injured worker had two DOI's. The first was 7/16/06. It was reported as a slip and fall with a no time loss right ankle injury. The second was 3/11/08 associated with water on the floor a slip and fall onto her buttocks onto wood, falling backwards striking her head with subsequent problems with her neck and low back. No orthopedic notes or radiologic investigations appeared to be available for review. However a very comprehensive AME psychiatric note in relation to a diagnosis of depression provided many details. The patient reported to her PCM with an exacerbation of her pain right ankle, neck and back. She was requesting a return to medications that had helped her get over significant flares in the past. This apparently included Ultracet as well as Naprosyn and Omeprazole (since she had GI symptoms while on NSAID's). At her presentation to the primary treating provider she was reported to have been on no prescription medications. The psychiatric review 1Jul15 however indicated her provider had recommended OTC Naprosyn and Omeprazole. If their use was associated with a compensable injury it is unclear why she was not already on these medications. The member had been working as a housekeeper. According to the psychiatric note she had worked at a [redacted] facility from 9/13 through to a new job she had been at with a [redacted] for a little over a month at her appointment with the AME. The psychiatrist diagnosed a major depression and recommended Effexor XR 150 qd. The patient made reference to some radiologic investigations (MRI) that suggested disk disease in the neck and low back. She reported that she could not stand in one place for any length of time without experiencing pain shooting down her legs associated with numbness. Extension of her neck caused pain and forward flexion of her back along with carrying objects worsened her low back pain. At the treating provider visit of 7/16/15 the diagnosis was a severe flare in pain with a background history of severe chronic lumbar, cervical and right ankle pain. At presentation the pain was listed as 7-9/10. Her baseline neck pain is 5/10, lumbar 3-4/10 and right ankle 6/10. The examination at that time listed moderate to severe tenderness over the L4-5 and L5-S1 spinous processes with associated paravertebral muscle guarding. Lumbar ROM is listed as 50-60% of normal. The right ankle had a reduced

ROM to approximately 70% of normal with palpable lateral tenderness but no swelling, edema or skin discoloration. Flex and Ext of the knee was 5/5.There were no details provided in terms of the past approaches to her medical management other than she reported that her treating provider had changed approximately once a year, was given topical treatments (type unknown) and told she needed surgery on the ankle but was never referred to an orthopedist. From the report it would appear that the member was familiar with the medications being prescribed. It is unclear why the Naprosyn was being prescribed when OTC Naprosyn already required use of a PPI to control GI symptoms. Ultracet is a fixed combination of Tramadol and Acetaminophen 32.5/325. Recommendations are for 2 q4-6h prn to a maximum of 8 per day and a maximum of 5 days. If the need to use a PPI was related to GI intolerance of Naprosyn as well as the need for breakthrough pain management it is unclear why Acetaminophen alone with Tramadol (single agent) on a prn basis to manage the breakthrough pain could not be used to eliminate the need for a second medication with long term side effects of their own (PPI's). Ultracet (Tramadol37.5/Acetaminophen 325) is recommended at 2 tabs q4-6h prn to a maximum of 8 tabs a day and a total of 5 days only. The proposed request does not match those FDA recommended limitations. Opioids are not recommended as first line agents for analgesia. For analgesia acetaminophen and NSAID's are considered to be our initial agents of choice. For short term relief opioids can be efficacious. Tr amadol has been found to provide pain relief but not functional improvement. However this class of agent is associated with significant risks. These risks include tolerance, hyperalgesia and abuse. It is estimated that chronic use is associated with a risk for substance use disorder of between 36 and 56%. There is no evidence for long term benefit or improvement in function. Rather than pain, consideration of level of functioning, quality of life and activities of daily living should be evaluated. Acetaminophen can be recommended for treatment of chronic pain & acute exacerbations of chronic pain. With new information questioning the use of NSAIDs, acetaminophen should be recommended on a case-by-case basis. The GI side effect profile of NSAIDs would have a bearing in this case. The use of Tramadol as a single agent would be potentially beneficial for breakthrough pain if and when the Acetaminophen does not prove to be sufficiently efficacious. The UR Non-Cert for Ultracet is supported. Therefore the request is not medically necessary.

60 Naproxen (anaprox) 550mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Acetaminophen, Antidepressants for chronic pain, Antiepilepsy drugs (AEDs), NSAIDs (non-steriodal anti-inflammatory drugs), NSAIDs, GI symptoms & cardiovascular risk, NSAIDs, specific drug list & adverse effects, Opioids (Classification).

Decision rationale: The injured worker had two DOI's. The first was 7/16/06. It was reported as a slip and fall with a no time loss right ankle injury. The second was 3/11/08 associated with water on the floor a slip and fall onto her buttocks onto wood, falling backwards striking her head with subsequent problems with her neck and low back. No orthopedic notes or radiologic investigations appeared to be available for review. However a very comprehensive AME psychiatric note in relation to a diagnosis of depression provided many details. The patient

reported to her PCM with an exacerbation of her pain right ankle, neck and back. She was requesting a return to medications that had helped her get over significant flares in the past. This apparently included Ultracet as well as Naprosyn and Omeprazole (since she had GI symptoms while on NSAID's). At her presentation to the primary treating provider she was reported to have been on no prescription medications. The psychiatric review 1Jul15 however indicated her provider had recommended OTC Naprosyn and Omeprazole. If their use was associated with a compensable injury it is unclear why she was not already on these medications. The member had been working as a housekeeper. According to the psychiatric note she had worked at a [redacted] facility from 9/13 through to a new job she had been at with a [redacted] for a little over a month at her appointment with the AME. The psychiatrist diagnosed a major depression and recommended Effexor XR 150 qd. The patient made reference to some radiologic investigations (MRI) that suggested disk disease in the neck and low back. She reported that she could not stand in one place for any length of time without experiencing pain shooting down her legs associated with numbness. Extension of her neck caused pain and forward flexion of her back along with carrying objects worsened her low back pain. At the treating provider visit of 7/16/15 the diagnosis was a severe flare in pain with a background history of severe chronic lumbar, cervical and right ankle pain. At presentation the pain was listed as 7-9/10. Her baseline neck pain is 5/10, lumbar 3-4/10 and right ankle 6/10. The examination at that time listed moderate to severe tenderness over the L4-5 and L5-S1 spinous processes with associated paravertebral muscle guarding. Lumbar ROM is listed as 50-60% of normal. The right ankle had a reduced ROM to approximately 70% of normal with palpable lateral tenderness but no swelling, edema or skin discoloration. Flex and Ext of the knee was 5/5.There were no details provided in terms of the past approaches to her medical management other than she reported that her treating provider had changed approximately once a year, was given topical treatments (type unknown) and told she needed surgery on the ankle but was never referred to an orthopedist? From the report it would appear that the member was familiar with the medications being prescribed. It is unclear why the Naprosyn was being prescribed when OTC Naprosyn already required use of a PPI to control GI symptoms. Ultracet is a fixed combination of Tramadol and Acetaminophen 32.5/325. Recommendations are for 2 q4-6h prn to a maximum of 8 per day and a maximum of 5 days. If the need to use a PPI was related to GI intolerance of Naprosyn as well as the need for breakthrough pain management it is unclear why Acetaminophen alone with Tramadol (single agent) on a prn basis to manage the breakthrough pain could not be used to eliminate the need for a second medication with long term side effects of their own (PPI's). Both acetaminophen and NSAIDs have been recommended as first line therapy for low back pain. There is insufficient evidence to recommend one medication over the other. Selection should be made on a case-by- case basis based on weighing efficacy vs. side effect profile. In the past many low back pain guidelines recommended acetaminophen as a first line treatment but there are problems with research in this area that include a lack of large high quality trials, inadequate reporting of methods and results, and choice of treatment contrasts. It appears that part of the reason that acetaminophen was recommended as a first-line treatment over NSAIDs in most guidelines, in part, was that acetaminophen appeared to have less adverse effects which bears specifically on this case. A decision in favor of Acetaminophen would make sense in light of the Non-Cert for Ultracet and recommendation to use Acetaminophen and consider simple Tramadol as backup for breakthrough pain. Avoiding Naprosyn would help to avoid the need for a second agent (PPI) with long term side effect problems of their own. Additionally this patient has back pain that with prolonged standing radiates down the legs and is associated with numbness. This implies a neuropathic pain better handled by AED's or ADD's. In this case the patient has been

started on Venlafaxine for her depression. Venlafaxine is recommended as an option in first-line treatment of neuropathic pain. The UR Non-Cert for Naprosyn is supported. Therefore the request is not medically necessary.

60 Prilosec 20mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Acetaminophen, Antidepressants for chronic pain, Antiepilepsy drugs (AEDs), NSAIDs, GI symptoms & cardiovascular risk, NSAIDs, specific drug list & adverse effects, Opioids (Classification), Venlafaxine (Effexor).

Decision rationale: The injured worker had two DOI's. The first was 7/16/06. It was reported as a slip and fall with a no time loss right ankle injury. The second was 3/11/08 associated with water on the floor a slip and fall onto her buttocks onto wood, falling backwards striking her head with subsequent problems with her neck and low back. No orthopedic notes or radiologic investigations appeared to be available for review. However a very comprehensive AME psychiatric note in relation to a diagnosis of depression provided many details. The patient reported to her PCM with an exacerbation of her pain right ankle, neck and back. She was requesting a return to medications that had helped her get over significant flares in the past. This apparently included Ultracet as well as Naprosyn and Omeprazole (since she had GI symptoms while on NSAID's). At her presentation to the primary treating provider she was reported to have been on no prescription medications. The psychiatric review 1Jul15 however indicated her provider had recommended OTC Naprosyn and Omeprazole. If their use was associated with a compensable injury it is unclear why she was not already on these medications. The member had been working as a housekeeper. According to the psychiatric note she had worked at a [redacted] facility from 9/13 through to a new job she had been at with a [redacted] for a little over a month at her appointment with the AME. The psychiatrist diagnosed a major depression and recommended Effexor XR 150 qd. The patient made reference to some radiologic investigations (MRI) that suggested disk disease in the neck and low back. She reported that she could not stand in one place for any length of time without experiencing pain shooting down her legs associated with numbness. Extension of her neck caused pain and forward flexion of her back along with carrying objects worsened her low back pain. At the treating provider visit of 7/16/15 the diagnosis was a severe flare in pain with a background history of severe chronic lumbar, cervical and right ankle pain. At presentation the pain was listed as 7-9/10. Her baseline neck pain is 5/10, lumbar 3-4/10 and right ankle 6/10. The examination at that time listed moderate to severe tenderness over the L4-5 and L5-S1 spinous processes with associated paravertebral muscle guarding. Lumbar ROM is listed as 50-60% of normal. The right ankle had a reduced ROM to approximately 70% of normal with palpable lateral tenderness but no swelling, edema or skin discoloration. Flex and Ext of the knee was 5/5.There were no details provided in terms of the past approaches to her medical management other than she reported that her treating provider had changed approximately once a year, was given topical treatments (type unknown) and told she needed surgery on the ankle but was never referred to an orthopedist? From the report it would appear that the member was familiar with the medications being prescribed.

It is unclear why the Naprosyn was being prescribed when OTC Naprosyn already required use of a PPI to control GI symptoms. Ultracet is a fixed combination of Tramadol and Acetaminophen 32.5/325. Recommendations are for 2 q4-6h prn to a maximum of 8 per day and a maximum of 5 days. If the need to use a PPI was related to GI intolerance of Naprosyn as well as the need for breakthrough pain management it is unclear why Acetaminophen alone with Tramadol (single agent) on a prn basis to manage the breakthrough pain could not be used to eliminate the need for a second medication with long term side effects of their own (PPI's). When attempting to determine the risk for gastrointestinal events the following risk factors should be taken into consideration: age 65 years, history of peptic ulcer, GI bleeding or perforation, concurrent use of ASA, corticosteroids, and/or an anticoagulant; or high dose/multiple NSAID (e.g., NSAID low-dose ASA). Patients with no risk factor and no cardiovascular disease would be considered safe to use a Non-selective NSAIDs such as Naprosyn. Patients at intermediate risk for gastrointestinal events and no cardiovascular disease: A non-selective NSAID with either a PPI or a Cox-2 selective agent such as Celebrex. In this situation the patient does not reach the intermediate level and would not warrant the use of a PPI. If seriously concerned about the complaint of pain with taking medications ascertaining what sorts of medications would be important and if it was a non-selective NSAID then Celebrex may have been a better choice than Naprosyn to both minimize symptoms, simplify the patients medication regimen as well as lower her overall cost of medications and risk of additional side effects related to long term PPI use. Acetaminophen can be recommended for treatment of chronic pain & acute exacerbations of chronic pain. With new information questioning the use of NSAIDs, acetaminophen should be recommended on a case-by-case basis. It would appear that an NSAID would not be an appropriate choice for this patient's neuropathic pain management. Venlafaxine is recommended as an option in first-line treatment of neuropathic pain and has already been initiated to help manage her diagnosis of major depression. The members risk factor analysis does not rise to the intermediate level, the Naprosyn request has been Non-Cert, Acetaminophen would be a reasonable option and the Venlafaxine is approved for both diabetic neuropathy and managing neuropathic pain. In sum the PPI is unnecessary and the UR Non-Cert is supported. Therefore the request is not medically necessary.

One consultation/evaluation for chronic pain functional rehab program: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Introduction, Chronic pain programs (functional restoration programs), Functional restoration programs (FRPs), Psychological evaluations, IDDS & SCS (intrathecal drug delivery systems & spinal cord stimulators), Venlafaxine (Effexor).

Decision rationale: The injured worker had two DOI's. The first was 7/16/06. It was reported as a slip and fall with a no time loss right ankle injury. The second was 3/11/08 associated with water on the floor a slip and fall onto her buttocks onto wood, falling backwards striking her head with subsequent problems with her neck and low back. A very comprehensive AME psychiatric note in relation to a diagnosis of depression provided many details. The patient

reported to her PCM with an exacerbation of her pain right ankle, neck and back. The psychiatric review 1Jul15 indicated her provider had recommended OTC Naprosyn and Omeprazole. The member had been working as a housekeeper. According to the psychiatric note she had worked at a [redacted] facility from 9/13 through to a new job she had been at with a [redacted] for a little over a month at her appointment with the AME. The psychiatrist diagnosed a major depression and recommended Effexor XR 150 qd. At the treating provider visit of 7/16/15 the diagnosis was a severe flare in pain with a background history of severe chronic lumbar, cervical and right ankle pain. At presentation the pain was listed as 7-9/10. Her baseline neck pain is 5/10, lumbar 3-4/10 and right ankle 6/10. The examination at that time listed moderate to severe tenderness over the L4-5 and L5-S1 spinous processes with associated paravertebral muscle guarding. Lumbar ROM is listed as 50-60% of normal. The right ankle had a reduced ROM to approximately 70% of normal with palpable lateral tenderness but no swelling, edema or skin discoloration. Flex and Ext of the knee was 5/5. From the report it would appear that the member was familiar with the medications being prescribed. It is unclear why the Naprosyn was being prescribed when OTC Naprosyn already required use of a PPI to control GI symptoms. Ultracet is a fixed combination of Tramadol and Acetaminophen 32.5/325. Recommendations are for 2 q4-6h prn to a maximum of 8 per day and a maximum of 5 days. If the need to use a PPI was related to GI intolerance of Naprosyn as well as the need for breakthrough pain management it is unclear why Acetaminophen alone with Tramadol (single agent) on a prn basis to manage the breakthrough pain could not be used to eliminate the need for a second medication with long term side effects of their own (PPI's). Studies have shown that the longer a patient remains out of work the less likely he/she is to return. Similarly, the longer a patient suffers from chronic pain the less likely treatment, including a comprehensive functional restoration multidisciplinary pain program, will be effective. In this circumstance the patient did return to work and had apparently been employed in a series of housekeeping jobs and at least from 9/13 [redacted]. Success with a functional restoration usually reflects early identification. Factors that help identify at-risk patients include: (1) those unresponsive to conservative therapies demonstrated to be effective for specific diagnoses; (2) significant psychosocial factors negatively impacting recovery; (3) loss of employment or prolonged absence from work; (4) previous history of delayed recovery or rehabilitation; (5) lack of employer support to accommodate patient needs; and (6) a history of childhood abuse (verbal, physical, mental). Of these factors, lost time from work has the highest value in predicting those patients who will experience delayed recovery. In this case the patient is reported as working, having presented with a flare in pain. Of note the onset of the most recent injury dates to 2008 suggesting we are not dealing with early intervention. She does manifest a significant psychosocial factor with her diagnosis in July 2015 with a major depression for which specific treatment was initiated. In a large RCT the benefits of improved depression care (antidepressant medications and/or psychotherapy) extended beyond reduced depressive symptoms and included decreased pain as well as improved functional status. In addition the selected antidepressant, Venlafaxine is recommended as an option in first-line treatment of neuropathic pain. Venlafaxine (Effexor) is a member of the selective-serotonin and norepinephrine reuptake inhibitor (SNRIs) class of antidepressants. It has FDA approval for treatment of depression and anxiety disorders. It is off-label recommended for treatment of neuropathic pain, diabetic neuropathy, fibromyalgia, and headaches. Considering her additional diagnosis this may have additional benefits. In light of her continuing employment status, the duration of her chronic pain, diagnosis of depression with initiation of appropriate medication for both the depression and neuropathic pain along with a

diagnosis of diabetes it would appear that the consultation /evaluation for a chronic pain functional rehabilitation program is premature. The UR Non-Cert is supported. Therefore the request is not medically necessary.